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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,316	07/17/2003	Robert W. Childers	DI-5766	3437

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BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DF2-2E
DEERFIELD, IL 60015

EXAMINER	
CHAPMAN, GINGER T	
ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
08/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,316	CHILDERS ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *27-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-21 and 23-26* is/are rejected.

7)☒ Claim(s) *15 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. Claims 1-61 are pending in the application; claims 27-61 are withdrawn from consideration as being directed to nonelected inventions.

Terminal Disclaimer

2. The terminal disclaimer filed on July 27, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 7,241,272 B2 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1-4, 6, 7, 12, 14, 16, 17 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts (US 5,944,684).

5. With respect to claim 1, as best depicted in Figure 2, Roberts discloses a system for providing dialysis comprising: a patient fluid loop (c. 7, ll. 55-60) including a first pump 8a and multiple patient lumens (c. 8, l. 7); a second fluid loop including a second pump 8c and a medical fluid regenerator 11; a membrane device 10 in fluid contact with and separating the

patient fluid loop and the second fluid loop, the membrane device 10 allowing at least one selected component of the fluid in the patient fluid loop to transfer to the second fluid loop (c. 6, ll. 12-13 and c. 3, ll. 40-50);the second loop being closed except for the transfer of the selected component via the membrane device 10 (c. 8, ll. 55-57; c. 6, ll. 49-50; fig. 2); and a controller that operates the first 8a and second 8c pumps to recirculate fluid in the patient loop and the second loop (c. 8, ll. 2-5).

6. With respect to claim 2, Roberts discloses the membrane device 10 is a dialyzer (c. 5, ll. 66-67 to c. 6, ll. 1-2).

7. With respect to claim 3, Roberts discloses a pressure gradient exists across a membrane device (c. 6, l. 33; c. 4, l. 14).

8. With respect to claim 4, Roberts discloses the patient loop is closed except for the transfer of the selected component via the membrane device (c. 7, ll. 25-30).

9. With respect to claim 6, Roberts discloses the medical fluid regenerator includes a uremic toxin sorbent (c. 8, l. 51-52; c. 3, ll. 41-45).

10. With respect to claim 7, Roberts discloses the medical fluid regenerator includes at least one of: urease, zirconium phosphate, zirconium oxide and carbon (c. 3, ll. 45-50; c. 6, ll. 15-20).

11. With respect to claim 12, Roberts discloses peritoneal dialysis fluid is circulated through the patient fluid loop (c. 7, ll. 54-55).

12. With respect to claim 14, Roberts discloses at least parts of the patient fluid loop and the second fluid loop are provided in a disposable device (c. 3, ll. 50-52 and ll. 61-62; c. 7, ll. 29-31).

13. With respect to claim 16, Roberts discloses the controller enables fluid flow in opposite directions through the multiple patient lumens (c. 8, ll. 7-9).

14. With respect to claim 17, Roberts discloses a dual lumen catheter (c. 8, ll. 7-8).

15. With respect to claim 24, as best depicted in Figure 2, Roberts teaches an ultrafiltrate container 11 in fluid communication with at least one of the patient and second fluid loops (c. 7, ll. 58-60).

16. With respect to claim 25, Roberts discloses a fluid concentrate container 12 in fluid communication with at least one of the patient and second fluid loops (c. 7, ll. 60-61).

17. With respect to claim 26, Roberts discloses a controller operates the first pump 8a continuously to pump fluid into and out of a patient (c. 8, ll. 7-11).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al ('684).

21. With respect to claim 5, Roberts discloses the claimed invention except expressly disclosing the membrane device includes a nanofilter. Roberts, at c. 3, ll. 10-15, teaches the filter having a suitable pore size to separate the dialysate into ultrafiltrate and protein-containing fractions, thus providing motivation to select a filter size for the desired component and intended use. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the membrane device of Roberts with the claimed size filter since it would be within the general skill of a worker in the art to select a known size filter on the basis of its suitability for the intended use. Additionally, all filters perform the substantially identical function in the substantially identical manner, i.e. separating out selected matter or particles or other material by passing liquid or gas through a porous mass is a well-known function of essentially all filtering devices; the Federal Circuit has held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert denied*, 469 U.S. 830, 225 USPQ 232 (1984).

22. With respect to claim 13, Roberts teaches blood is circulated through the patient fluid loop (c. 7, ll. 1-4, teaching therapeutic agents reverse dialyzing into the bloodstream of the patient, the patient comprises an essential component of the patient fluid loop, blood is circulating through the patient, ergo inevitably and necessarily blood is circulating through the

patient fluid loop). Additionally, the examiner notes that during hemodialysis blood is channeled to a dialyzer comprising a patient fluid loop, as is known in the dialysis art. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made that either peritoneal dialysis fluid or blood can be circulated through the patient fluid loop since it is known in the art that for any particular patient in a renal / kidney disease patient population, the selection of hemodialysis or peritoneal dialysis would be an obvious modification of treatment made by the treating physician on a case-by-case basis depending on whether the risks of each form of dialysis treatment are outweighed by the benefits of treatment.

23. Claims 8-10 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Savitz et al (US 4,229,299).

24. With respect to claim 8, Roberts discloses the claimed invention except for a gas separator and gas vent. Savitz teaches a dialysis system comprising patient and second fluid loops C, A, gas separator 153, gas vent 154 and medical fluid regenerator 123. therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Roberts with the above noted components as taught by Savitz since Savitz states at c. 5, ll. 22-24 that the benefit of providing a gas separator and gas vent is that it prevents any gas from being returned with the blood to the patients body, and at c. 13, ll. 15-30, that the benefit of a gas vent is that the vent serves as an outlet for gas desolubilized from the system and additionally functions as an overflow discharge thereby providing a safer dialysis system.

25. With respect to claim 9, Roberts discloses the claimed invention except for the gas separator and medical fluid regenerator provided in a single device. Roberts teaches the medical

fluid regenerator and other components can be provided in a disposable cartridge (c. 7, ll. 29-31; c. 3, ll. 50-52 and ll. 61-62). In view of the teachings of Roberts it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the claimed components in a single device since it has been held that forming in one piece an article has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 US 164 (1893).

26. With respect to claim 10, Roberts discloses the claimed invention except a gas separator. Savitz teaches a dialysis system comprising a vent to selectively vent accumulated air from chambers 46 and 64. Therefore it would have been obvious ton one having ordinary skill in the art at the time the invention was made to provide the system of Roberts with a vent as taught by Savitz in order to prevent gas from being returned with the blood to the patient's body.

27. With respect to claims 18 and 19, Roberts discloses the claimed invention except for in-line fluid heaters comprising a radiant heater and a plate heater. Savitz, teaches in-line 129 fluid heaters 103, 152; and teaches at c. 12, ll. 28-30 that the heaters selected may be of any suitable type for the purpose of maintaining the dialysate solution at ~ normal body temperature. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Roberts with heaters of any suitable type as taught by Savitz since Svitz states, at c. 6, ll. 10-15, that the benefit of such a modification is that it prevents undue cooling or heating of the blood in contact with the dialysate and to prevent hemolysis thereby providing a safer dialysis system.

28. Claims 11 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Krivitski et al (US 5,685,989).

29. With respect to claims 11 and 20-21, Roberts discloses the claimed invention except for optical, fluid volume and capacitance sensors. Krivitski, at c. 4, ll. 24-27, teaches that optical, fluid volume and impedance, i.e. capacitance, sensors are known to measure change of characteristics of blood flow through dialysis loops. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to select any of these known sensors because the prior art teaches these sensors provide equivalent means to measure characteristics of blood during dialysis and it has been held that substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency. *In re Fount*, 213 USPQ 532 (CCPA 1982); *In re Siebentritt*, 152 USPQ 618 (CCPA 1967).

Allowable Subject Matter

30. Claims 15 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

31. The following is a statement of reasons for the indication of allowable subject matter:

32. With respect to claim 15, the prior art teaches second fluid loops that are closed in order to regenerate the dialysate solution and thereby reduce the amount of dialysate used in the system to reduce the cost of treatment; the subject matter not found in the prior art is the system comprising a patient fluid loop and a closed second fluid loop in combination with the second fluid loop comprising a balance chamber, which requires an increased volume of dialysate solution used during the filling / emptying cycle of fluid within the chamber.

33. With respect to claim 22, the subject matter not found in the prior art is a closed second fluid loop in combination with a chamber in fluid communication with at least one of the fluid loops wherein a capacitance fluid volume sensor uses the chamber in fluid communication with the fluid loop, see claim 15, *supra*.

Response to Arguments

34. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

35. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

36. Strahilevitz (US 6,602,502 B1): Figure 6 teaches a second fluid loop closed except for the transfer of a selected component of the fluid in the patient fluid loop to transfer to the second fluid loop.

37. Vijayalakshmi et al (US 6,746,607 B1): Figure 1 teaches a second fluid loop closed except for the transfer of a selected component of the fluid in the patient fluid loop to transfer to the second fluid loop.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
8/2/08

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761